

Form PTO-1449 U.S. Department of Commerce  
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.

A32362

072396.0174

Serial No.

09/320,767

## INFORMATION DISCLOSURE

## STATEMENT

## BY APPLICANT

(Use several sheets if necessary)

Applicant

Giannoukakis et al.

Filing Date

May 27, 1999

Group

1643

## U.S. PATENT DOCUMENTS

*Ex am. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate

## FOREIGN PATENT DOCUMENT

Document No.	Date	Country	Class	SubClass	Translator Yes No

## OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

56	Anderson, W. F. (1998). Human gene therapy. Nature 392, (6679 Suppl) 25-30.
58	Iwahashi, H., Itoh, N., Yamagata, K., Imagawa, A., Nakajima, H., Tomita, K., Moriwaki, M., Waguri, M., Yamamoto, K., Miyagawa, J., <i>et al.</i> (1998). Molecular mechanisms of pancreatic beta-cell destruction in autoimmune diabetes: potential targets for preventive therapy. Cytokines Cell Mol Ther 4, 45-51.
64	Evans, C. H., and Robbins, P. D. (1994). The interleukin-1 receptor antagonist and its delivery by gene transfer. Receptor 4, 9-15.

Examiner

Date Considered

12-10-04

\* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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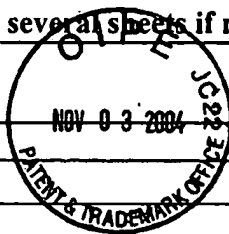
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49	6 2 6 8 1 9 4	7/31/01	Karin et al.			

**FOREIGN PATENT DOCUMENT**

Document No.	Date	Country	Class	SubClass	Translator Yes No
60/ 9 7 3 0 0 8 3	8/21/97	WO			
65/ 9 2 1 2 7 2 4	8/6/92	WO			

**OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)**

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51	Verma, I. M. (2000). Gene therapy: beyond 2000. Mol Ther 1, 493.
52	Giannoukakis, N., Mi, Z., Gambotto, A., Eramo, A., Ricordi, C., Trucco, M., and Robbins, P. (1999). Infection of intact human islets by a lentiviral vector. Gene Ther 6, 1545-1551.
53	Giannoukakis, N., Rudert, W. A., Ghivizzani, S. C., Gambotto, A., Ricordi, C., Trucco, M., and Robbins, P. D. (1999). Adenoviral gene transfer of the interleukin-1 receptor antagonist protein to human islets prevents IL-1beta-induced beta-cell impairment and activation of islet cell apoptosis in vitro. Diabetes 48, 1730-1736.
54	Giannoukakis, N., Rudert, W. A., Robbins, P. D., and Trucco, M. (1999). Targeting autoimmune diabetes with gene therapy. Diabetes 48, 2107-2121.
55	Grey, S. T., Arvelo, M. B., Hasenkamp, W. M., Bach, F. H., and Ferran, C. (1999). Adenovirus-mediated gene transfer of the anti-apoptotic protein A20 in rodent islets inhibits IL-1 beta-induced NO release. Transplant Proc 31, 789.
56	Anderson, W. F. (1998). Human gene therapy. Nature 392, (6679 Suppl) 25-30.

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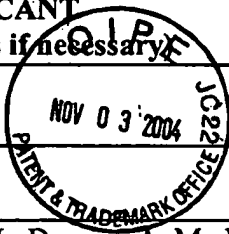
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| 57 | Harrison, M., Dunger, A. M., Berg, S., Mabley, J., John, N., Green, M. H., and Green, I. C. (1998). Growth factor protection against cytokine-induced apoptosis in neonatal rat islets of Langerhans: role of Fas. <i>FEBS Lett</i> 435, 207-210.  |
| 58 | <del>Iwahashi, H., Itoh, N., Yamagata, K., Imagawa, A., Nakajima, H., Tomita, K., Moriwaki, M., Waguri, M., Yamamoto, K., Miyagawa, I., et al. (1998). Molecular mechanisms of pancreatic beta-cell destruction in autoimmune diabetes: potential targets for preventive therapy. <i>Cytokines Cell Mol Ther</i> 4, 45-51.</del> |
| 59 | Loweth, A. C., Williams, G. T., James, R. F., Scarpello, J. H., and Morgan, N. G. (1998). Human islets of Langerhans express Fas ligand and undergo apoptosis in response to interleukin-1beta and Fas ligation. <i>Diabetes</i> 47, 727-732.  |
| 61 | Verma, I. M., and Somia, N. (1997). Gene therapy -- promises, problems and prospects. <i>Nature</i> 389, 239-242.  |
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| 63 | Welsh, N., Bendtzen, K., and Welsh, M. (1995). Expression of an insulin/interleukin-1 receptor antagonist hybrid gene in insulin-producing cell lines (HIT-T15 and NIT-1) confers resistance against interleukin-1-induced nitric oxide production. <i>J Clin Invest</i> 95, 1717-1722.  |
| 64 | <del>Evans, C. H., and Robbins, P. D. (1994). The interleukin-1 receptor antagonist and its delivery by gene transfer. <i>Receptor</i> 4, 9-15.</del>  |

The PTO did not receive the following  
listed items(s)

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12-10-07

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